



January 16, 2024

**VIA CM/ECF**

Honorable Nathaniel M. Gorton  
U.S. District Court for the District of Massachusetts  
1 Courthouse Way  
Boston, MA 02210

Re: *Iron Workers Dist. Council of New Engl. v. Teva Pharm. Indus. Ltd.*, No. 23-cv-11131-NMG (D. Mass.): Request for Judicial Notice

Your Honor:

The plaintiffs previously requested that the Court take judicial notice of the Federal Trade Commission's warning letters to Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. concerning the companies' Orange Book listings for several products, including QVAR and QVAR ReditHaler.<sup>1</sup> The plaintiffs now write to advise the Court of additional developments.

In those warning letters, the FTC invoked the Food and Drug Administration's patent listing dispute process.<sup>2</sup> Teva's and Norton's responses to the dispute were due on December 16, 2023.<sup>3</sup> Teva and Norton responded on January 5, 2024, and "no Orange Book changes" were made.<sup>4</sup>

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<sup>1</sup> Pls.' Opp'n to Defs.' Mot. Dismiss 5 n.34, ECF No. 40.

<sup>2</sup> Letter, FTC to Teva Branded Pharm. Prods. R&D, Inc. (Nov. 7, 2023), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/teva-branded-pharma-orange-book.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/teva-branded-pharma-orange-book.pdf); Letter, FTC to Norton (Waterford) Ltd. (Nov. 7, 2023), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/norton-orange-book.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/norton-orange-book.pdf). Under that process, the FDA does not independently assess a challenged listing. 21 C.F.R. § 314.53(f)(1)(i) ("Unless the NDA holder withdraws or amends its patent information in response to the patent listing dispute, the Agency will not change the patent information in the Orange Book."); see *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) ("[The FDA] . . . administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents."). Instead, it advises the New Drug Application ("NDA") holder of the dispute, and the NDA holder must, within 30 days, either (i) withdraw the patent listings, (ii) amend the patent listings, or (iii) recertify that the listings are proper. See 21 C.F.R. § 314.53(f)(1)(i)(B).

<sup>3</sup> See FDA, *Patent Listing Disputes*, <https://www.fda.gov/media/105080/download?attachment> (Updated Jan. 12, 2024).

<sup>4</sup> *Id.* (cleaned up); see also 21 C.F.R. § 314.53(f)(1) (requiring that a NDA holder that purports to "confirm[]" the correctness" of the patent listings must "include[]" the signed verification required by paragraph (c)(2)(ii)(R) of" 21 C.F.R. § 314.53); see also 21 C.F.R. § 314.53(c)(2)(ii)(R) (requiring verification "under penalty of perjury").

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The plaintiffs respectfully request that the Court take judicial notice of these developing facts, which appear in official public records:<sup>5</sup> there is no reasonable dispute as to those records' authenticity, and Teva's and Norton's recertifications are central to the plaintiffs' claims.<sup>6</sup>

Additionally, on January 8, 2024, the United States Senate Committee on Health, Education, Labor, and Pensions commenced an investigation into the high cost of inhaled medications, including Teva's QVAR and QVAR Redihaler products. The Committee sent a letter to Teva Pharmaceutical Industries, Ltd. concerning the investigation.<sup>7</sup> The plaintiffs also respectfully request that the Court take judicial notice of the fact of the investigation and the Committee's letter to Teva.<sup>8</sup>

Respectfully submitted,



**BERMAN TABACCO**

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Cc: All counsel (via CM/ECF)

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<sup>5</sup> 21 C.F.R. § 314.53(f)(1)(B)(iii) (requiring FDA to “post information on its Web site regarding whether a patent listing dispute has been submitted . . . and whether the NDA holder has timely responded to the patent listing dispute”).

<sup>6</sup> *See Waterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993).

<sup>7</sup> *See, e.g.*, Letter, Senators Bernard Sanders, Tammy Baldwin, Ben Ray Luján, and Edward J. Markey to Richard Francis, President and CEO, Teva Pharm. Indus. Ltd. (Jan. 8, 2024), <https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-Teva.pdf>.

<sup>8</sup> *See Waterson*, 987 F.2d at 3.